Process Approach to Auditing

Joe Kirkpatrick

May 17, 2018
• Est. in 1963 by the Tennessee General Assembly
• One of five units of the Institute for Public Service
• Staff of 32 and 15-20 temporary employees
• TN’s NIST-Manufacturing Extension Partner (MEP) Center
A NATIONAL NETWORK HELPING MANUFACTURERS THRIVE

NATIONAL NETWORK
One Center in every state and Puerto Rico

Over 1,200 Experts

588 Field Locations

More Than 2,300 Service Providers

Helping Nearly 300,000 Manufacturers
Our Solutions Consultant Team Serving the State

Andre Temple  
Solutions Consultant (3)

Norma Wilcox  
Solutions Consultant (5)

Gordon Reed  
Solutions Consultant (6)

Dwaine Raper  
Team Leader

Misty DePriest  
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7.2.3 Internal auditor competency

Quality management system auditors, manufacturing process auditors, and product auditors shall all be able to demonstrate the following minimum competencies:

a) understanding of the automotive process approach for auditing, including risk-based thinking;
9.2.1

The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

9.2.2

The organization shall:

a) plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
IATF16949:2016

9.2.2.1 Internal audit program

The audit program shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).
9.2.2.2 Quality management system audit

The organization shall audit all quality management system processes over each three-year calendar period, according to an annual program, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.
9.2.2.2 Quality management system audit

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How do organizations define processes?
The Process Approach

- **Purpose**
- **Objectives**
- **Risks**
- **Process**
- **Results**
- **Outputs**

**Inputs**
- Stakeholder Wants & Needs
- Specifications
- Schedule/Timing
- Market Data
- Industry Trends
- Economic Conditions

**Outputs**
- Products
- Information
Customer Oriented Processes

This is a process

- An interface Organizational/External environment input (I)
- An interface Organizational/External environment output (O)

Notice how this is a literal application of the process model.

Check input against output.

Key
- Information flow
- Value-adding activities

Continual improvement of the quality management system

Management responsibility

Measurement, analysis and improvement

Product realization

Resource management

Input

Output

Customers

Satisfaction

Requirements

Product

Continual improvement of the quality management system

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Input

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Requirements

Product
The Octopus Model
Examples of COPs

- Finished Prototype
- Product Specifications Determined
- Production Run and Optimized
- Warranty Request
- Warranty Request Accepted
- Performance Reports
- Corrective actions, Preventive actions, Continual Improvement
- Sales and Marketing Research of Market
- Information about Product Line(s)
- Request for Quote from Customer
- Bid / Tender
- Market Analysis
- Customer Feedback
- Warranty
- Production Run and Optimized
- Product Realization
- Product Validation
- Prototype Delivered
- Prototype Requested
- Order / Request
- Order Accepted
- Bid Awarded with Specifications
- Bid Proposal
- Product Design
- Product Analyzed and Request for Change Issued
- Examples of COPs
The process approach and PDCA

Processes can be managed using the PDCA cycle

<table>
<thead>
<tr>
<th>Plan</th>
<th>set objectives and build processes necessary to deliver results</th>
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<tr>
<td>Do</td>
<td>implement what was planned</td>
</tr>
<tr>
<td>Check</td>
<td>monitor and measure processes and results against the objectives</td>
</tr>
<tr>
<td>Act</td>
<td>take actions to improve results</td>
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What are the possible benefits?

- Increases accountability
- Increases ability to focus and link key processes
- Improves internal integration of processes
- Increases awareness of process performance for more consistent results
- Better use of resources
- Improves customer confidence in the organization

All of these add value for the organization
Why do processed approach to auditing?

- Identifies linkages between processes as inputs / outputs.
- More efficient way to cover all the clauses of the ISO standard.
How can you define processes?

- Interaction maps
- SIPOC’s
- Turtle Diagrams
- Process Activity Diagrams
Automotive Process Approach Summary

The audit process shall verify that the organization has:

• Clearly identified the strategic direction
• Clearly identified the processes needed
• Clearly identified sequence and interaction
• Clearly identified process owners
• Clearly identified resources needed to ensure effective operation
• Clearly identified risk and opportunity and how they are addressed
• Clearly identified measures of process effectiveness and efficiency

FOCUS ON PERFORMANCE
SIPOC Diagram

SIPOC DIAGRAM          Process: Corrective Action       Rev. 9/19/16
Process Owner:  Jeff Smith       Measureable: # of Customer Complaints, % of C/A completed ontime, # of repeat c/a’s

Supplier
Customer (Internal or External)
Non-conformance report
Email from sales or customer
Phone call from Sales or Customer

Input
Customer (Internal or External)
Non-conformance report

Process
Receive NC from Customer
Log NC into IQC sharepoint
Review IQC, assign responsibility
Perform root cause analysis per customer requirements
Develop corrective action
Implement Corrective Action
Verify Corrective Action
Was CA Effective?

Output
Yes
Send CA Report to Customer
Close CA
No

Customer
Record of NC
Email from sales or customer
Contact Customer
Alo Quality, Management

Alo Quality
Non-conformance report

Supplier Quality Manuel
Defective material
NC Report
Measurement reports
Drawings

Customer
Alo Quality
Customer
Supplier Quality Manuel
Defective material
NC Report
Measurement reports
Drawings

Quality, Customer
Alo Quality
Alo Quality, Management
Engineering
Alo employees
Alo management
Alo quality
**Process Audit Diagram**

**Management Processes**

1. **Name of your Process & Owner?**
   - Owner:

2. **Process Inputs**
   - What goes into your process?

3. **Process Outputs**
   - What comes out of your process?

4. **With What Key Criteria (Measurement/Assessment)**
   - How does the company measure performance results?

5. **How? (Methods/Procedures/Techniques)**
   - What methods are used to produce product or service?

   - What materials & Equipment are Used?

7. **With Whom? (Competence/Skills/Training)**
   - Who Does Work & What is Method of Determining Competencies / Skills?
Process Audit Diagram

Center for Industrial Services
INSTITUTE FOR PUBLIC SERVICE

(Audit Planning Tool)
Gages
Visual inspection

MRB

Sales
Quality

Defective Product
Customer Complaints
ECN
Tags

N/C Material
J. Wicker
Owner:

Process Outputs
Rework prod
C/A
N/C Log
Scrap
Deviation
Insp record

Key Process Steps
MRB
Rework
Re-insp

With What? (Materials/Equipment)
Gages
Visual inspection

With What? (Measurement/Assessment)
FTT / DOT

With Whom? (Competence/Skills/Training)
MRB
Sales
Quality

With What Key Criteria (Measurement/Assessment)
FTT / DOT
Process Approach Auditing

How should you interview the process owner?

- What should you ask?
- Do you have a procedure for your process?
- Could you please describe the process?
- How do you know the process is working effectively?
- How do you know how to start the process?
- What are the inputs and outputs of the process?
- What resources are used with this process?
  - Tools
  - Measuring devices
  - Machinery
Process Approach Auditing

Conducting a value added process based audit is not easy

- **Avoid just** auditing on the audit standard
- Do not ask questions off the top of your head. Your questions need to be based on your knowledge of the audit standard and the companies processes.
- Always verify/validate the companies internal procedures.
- Assess how the company established, measure and communicates objectives.
- Verify conformance to the standard as your complete each audit of a process – **note first bullet**.
Process Approach Auditing

1. Establish or define your processes.
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Process Approach Auditing

2. Document what procedures or process maps are associated with each process.
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Process Approach Auditing

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Process Approach Auditing

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Process Approach Auditing

How much time do you prepare for the audit?

How much time do you actually audit?

How much time do you write up report?
What audit criteria should be audit against?

Standards – ISO / IATF
Procedures, Processes, Policies
Customer Specific Requirements
Past Audit Results
Past Corrective Actions (related to process being audited)
Past Customer Complaints (related to process being audited)
Internal issues (related to process being audited)
Control Plans
FMEA’s
Statutory / Regulatory Requirements
Why do we audit processes?

To ensure that...

- we meet the QMS Standard Requirements
- documented procedures/WI’s are available to fulfill the requirement (complete and controlled?)
- necessary resources are provided
- personnel are assigned to the function (trained? qualified?)
- controls are implemented to measure process parameters and performance
- the function is being performed (per procedure?)
- records provide evidence (controlled?)
- the process as implemented is effective (i.e., we find evidence that the process is capable of consistently producing the desired results
IATF rules state we should:

- questioning processes, the sequence and interactions, and performance against the measures defined
- focus on processes which directly impact the customer
- questioning the process objectives/targets, with focus on where targets are not being met
- focus on issues that have the greatest impact on the customer
- questioning what plans are in place to ensure targets are met
- corrective action plans where objectives are not being met
- following audit trails to linkages between customer concerns, performance against objectives and relevant process documents (e.g. control plan, FMEA, etc.),
- questioning the clients' process for gathering, communicating and implementing customer-specific requirements
Audit Schedule

Audit Plan